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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,571	12/31/2001	Etsuro Ogata	04853.0086	7887

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,571	OGATA ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,12-14,18,23,24 and 26-30* is/are pending in the application.

4a) Of the above claim(s) *4-8, 12, 13, 18, 23, and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,9,10,14 and 26-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicants' amendment filed on November 18, 2004 has been entered. Claims 1, 3, 9, and 14 have been amended. Claims 2, 11, 15-17, 19-22, and 25 have been canceled. Claims 26-30 have been added. Claims 1, 3-10, 12-14, 18, 23, 24, and 26-30 are pending. Claims 1, 3, 9, 10, 14, and 26-30 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

The objection to the disclosure set forth in (i) has been withdrawn in view of Applicants' argument; the objection to the disclosure set forth in (ii) has been withdrawn in view of Applicants' amendment to the specification.

The rejection of claims 1-3, 9-11, 14-17, 19-22, and 25 under 35 U.S.C. 112, second paragraph, as set forth in the previous office action (Paper No. 04222004, 05/18/2004), has been withdrawn in view of amended claim 1, cancelled claims 2, 11, 15-17, 19-22, and 25, and argument about the term "QOL".

The objection to claims 1-3, 9, 11, 14-17, 19-22, and 25 has been withdrawn in view of amended claims or cancelled claims.

Priority

Applicant is right in that the present application is a National Stage filing of a PCT and a certified copy of this application was filed with the International Bureau of WIPO. Thus, under PCT Rule 17.2, Applicant is not required to file a certified copy of the priority application to a designed office.

Claim Rejections Under 35 U.S.C. § 112, 1st Paragraph (Scope of Enablement)

The rejection of claims 1, 3, 9, 10, and 14 under 35 U.S.C. 112, 1st paragraph, as set forth at pages 5-9 of the previous office action (Paper No. 04222004, 05/18/2004), is maintained. New claims 26-30 are also rejected on the same basis.

At page 10 of Applicants' response, Applicants submit that Applicants have amended claims 1 and 3 and canceled the rejected claims 2, 11, 19, 21, and 25. Applicants argue that because the Examiner stated that the specification was enabling for a method of treating PTHrP-related septicemia with an anti-PTHrP antibody, Applicants request that the Examiner withdraw the enbalement rejection.

This has been fully considred, but is not deemed to be persuasive for the following reasons. As stated in the previous office action, the specification was enabling for a method of treating PTHrP-related septicemia with an anti-PTHrP antibody. However, independent claims 1 and 26 recite a method of treating or ***preventing*** septicemia comprising administering to a patient at least ***one humanized (or human) antibody that binds to a ligand of a PTHrP receptor*** to ***promote or inhibit*** binding between the

ligand and the receptor. Three key issues remain in the amended claims. First, as noted in the previous office action, the instant disclosure does not enable a method of preventing a disease, e.g., septicemia. Secondly, "a humanized antibody (or a human antibody) that binds to a ligand of a PTHrP receptor", as recited in the amended claims, is not limited to an anti-PTHrP antibody. The specification refers " a ligand" as a substance binding to an enzyme receptor (2nd paragraph of page 8 of the specification). PTH and PTHrP are only examples of the ligands (3rd paragraph of page 8 of specification). Except for an anti-PTHrP, the instant disclosure fail to teach how to make and use any other humanized antibodies (or human antibodies) that bind to a ligand of a PTHrP receptor for treating septicemia. Thirdly, since the amended claims recite only one disease, septicemia, treatment of septicemia can apparently be achieved only by the action of an anti-PTHrP antibody through inhibition (or promotion) of binding between PTHrP and its receptor. An anti-PTHrP antibody may not work either ways, promoting or inhibiting, in the treatment of septicemia. Accordingly, the scope of enablement set forth in the previous office action is maintained.

Claim Rejections Under 35 U.S.C. § 112, 1st Paragraph (Written Description)

The rejection of claims 1, 3, 9, 10, and 14 under 35 U.S.C. 112, 1st paragraph, as set forth at pages 9-11 of the previous office action (Paper No. 04222004, 05/18/2004), is maintained. New claims 26-30 are also rejected on the same basis.

At page 11 of Applicants' response, Applicants argue that the office action stated that the specification provided written description for the anti-PTHrP and anti-PTH antibodies

and thus claims, as amended, fullfill the written description requirement. This has been fully considered, but is not deemed to be persuasive because the amended claims recite "a humanized antibody (or a human antibody) that binds to a ligand of a PTHrP receptor", which is not limited to an anti-PTHrP or anti-PTH antibody. The specification refers " a ligand" as a substance binding to an enzyme receptor (2nd paragraph of page 8 of the specification). PTH and PTHrP are only examples of the ligands (3rd paragraph of page 8 of specification). As noted in the previous office, the specification fails to provide sufficient description information, such as definitive structural features of the genus of "ligand", and thus fails to provide sufficient description of a a humanized antibody (or a human antibody) that binds to a ligand of a PTHrP receptor.

Claim Rejections Under 35 USC § 102

(i) The rejection of claims 1, 3, 9, 10, and 14 under 35 U.S.C. 102(e) as being anticipated by Sato et al. (US2002/0165363 A1, Publication Date: November 7, 2002; earliest priority date: May 15, 1997), as set forth at page 13 of the previous Office Action (Paper No. 04222004, 05/18/2004), is maintained. New claims 26-30 are also rejected because Sato et al. teach a method of treating cachexia comprising administering to mice with cachexia an anti-PTHrP antibody, including a human antibody (see [0013]).

At page 11 of Applicants' response, Applicants argue that Sato et al. do not disclose the administration of a PTHrP antibody to treat or prevent septicemia. This has been fully considred, but is not deemed to be persuasive because Sato et al. teach a method of administering to a patient (mice with cachexia) a same agent (a humanized PTHrP

antibody or a human PTHrP antibody) as that of the instantly claimed method, the intended uses and properties of a PTHrP antibody recited in the claims are inherent to the method taught by Sato et al.

(ii) The rejection of claims 1, 3, 9, 10, and 14 under 35 U.S.C. 102(b) as being anticipated by Grunfeld et al. (WO 96/39184, December 12, 1996), as set forth at page 13 of the previous Office Action (Paper No. 04222004, 05/18/2004), is maintained. New claims 26-30 are also rejected because Grunfeld et al. teach a method of treating septicemia with a human anti-PTHrP antibody (see bottom of page 5).

At top of page 14 of applicants' response, Applicants argue that Grunfeld et al. do not disclose or teach humanized antibodies. This has been fully considred, but is not deemed to be persuasive because Grunfeld et al. clearly teach humanized antibodies. For example, at page 5, lines 29-37, Grunfeld et al. states " the polyclonal or monoclonal antibodies may be raised in rabits, mice, or other animals or tissue cultured cells or can be products of cells of human origin. They may also be produced of recombinant DNA technology either in a form identical to that of the native antibody or as chimeric molecules, constructed by recombination of antibody molecules of man and animal origins or in other forms chosen to make the antibodies most suitable for use in therapy". Accordingly, the teachings of Grunfeld et al. anticipate claims 1, 3, 9, 10, 14, and 26-30.

Claim Objections

The objection to claim 10 for reciting non-elected subject matter (species) is maintained. Newly added claim 29 is also objected to for the same reason. Appropriate correction is required.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875.

The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li, Ph.D.
Examiner
January 24, 2005

JANET ANDRES
PRIMARY EXAMINER